REMARKS

Claims 1 and 8-13 are pending. Claim 1 has been amended. Support for the amended claims can be found throughout the specification, for example, at page 9, lines 24-26, in the sequence listing, and in the claims as originally filed. No new matter enters by way of these amendments.

I. Status

Applicants acknowledge that this application has been transferred from Examiner Arun Chakrabarti of Art Unit 1634 to Examiner Cynthia Wilder of Art Unit 1637.

An appeal brief was filed on March 9, 2004. The Examiner indicates, however, that "[a]ll of the arguments have been thoroughly reviewed and considered, but are deemed moot in view of the new grounds of rejections." Office Action at page 1. The Examiner further states that "[a]ny rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims."[1] *Id.* Applicants assume that the finality of the previous Office Action has been withdrawn and acknowledge that new grounds of rejection have been set forth in the present Office Action.

II. Rejection under 35 U.S.C. § 101

Claims 1 and 8-13 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well-

[1] Applicants note that no amendment to the claims has been filed subsequent to Final Office Action mailed October 9, 2003.

established utility. Office Action at page 3. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "molecule tags to isolate genetic regions, isolate genes, map genes and determine gene function..., in marker-assisted breeding programs..., as antibodies..., as primer and probes for the isolation of full length cDNAs or genes..., in mutation detection..., in the identification of polymorphism..., as molecular markers.., genetic mapping studies..., in DNA-protein interaction..., in methods of identifying chromosomes with translocation..., in method of protein-protein interaction..., in microarray based methods..., in site directed mutagenesis... and in methods of transformation." Office Action at pages 3-4. However, despite this admission and numerous additional uses cited throughout the specification, the Examiner contends that none of these utilities constitutes a "specific" or "substantial" utility. *Id.* at page 4. In particular, the Examiner alleges that the disclosed utilities are "generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed." *Id.* In addition, the Examiner contends that "further research is required to determine the specific utility of the claimed nucleic acid sequence." *Id.* Applicants respectfully disagree.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in

determining the presence or absence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* S*ee, e.g.,* specification, beginning at page 33, under heading "Uses of the Agents of the Invention".

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are "generally applicable to any nucleic acid," Office Action at page 4, and "not particular to the nucleic acid sequences being claimed." *Id.* In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions

which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

Moreover, the specification also discloses the isolation of the claimed nucleic acid molecules from the cDNA library SOYMON022 and that such cDNA library was prepared from partially to fully open flower tissue of soybean. Specification at page 33, lines 4-14 and page 85, line 20 through page 86, line 4 (Example 1). In addition, the specification describes methods used to analyze the claimed nucleic acid molecules and their association "involved in floral development, reproduction and seed production, ... genes that regulate meiosis, cell division, carotenoids, floral biogenesis, embryogenesis,

protein, amino acids, sterols, oils, minerals, isoflavones, saponins, vitamins, tocopherols, antinutrient components, carbohydrates, starch metabolism and seed regulatory elements." *See, e.g.,* specification at page 33, lines 4-14, in the Examples at page 85, *et seq.* and in the Sequence Listing. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify polymorphisms and markers and isolate promoters in soybean plants upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an

asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1 and 8-13 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled).[2] Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

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[2] Applicants note that "[c]laims 1-16 and 35-38" were rejected in the instant Office Action as not being enabled by the specification. Applications note that only claims 1 and 8-13 are pending in the instant application, *See, e.g.*, Office Action Summary, and therefore treat the recitation of "[c]laims 1-16 and 35-38" as a typographical error.

IV. Rejections under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1, and 8-13 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at pages 5-6. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the Applicants have "express possession" of SEQ ID NO: 5981. *Id.* at page 6. However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that "the disclosure of fragments or complements thereof of SEQ Id NO: 5981 encompass a large genus of nucleic acid sequence species that are not described in the specification or examples starting at page 85."[3] *Id.* at page 6. Apparently, the Examiner contends that the specification does not provide "[a] representative number of species for each genus" to satisfy the written description requirement. *Id.* Applicants respectfully traverse.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would,

after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 5981, and the complements and specified variations thereof. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 21, lines 11-17; page 25, line 8 through page 26, line 21; and page 38, line 7 through page 45, line 22). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 18, line 3 through page 19, line 16); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 21, line 18 through page 24, line 21); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 28, line 24 through 29, line 3); plant homologue proteins (*see, e.g.,* specification at page 20, line 11 through page 21, line 17); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 56, line 6 through page 57, line 18); vectors comprising the claimed nucleic acid molecules and methods of transforming

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Footnote continued from previous page

[3] Applicants note that to facilitate prosecution claim 1 has been amended to delete the recitation of "fragment thereof."

plants (*see, e.g.,* specification 61, line 8 through page 78, line 2); and construction of cDNA libraries using the claimed nucleic acid molecules (*see, e.g.,* specification at page 85, line 19 through page 89, line 3 (Examples 1-3)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "the specification fails to show that applicant was, in fact, 'in possession of the claimed invention', at the time the application for patent was filed." Office Action at page 7. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See, Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genera from non-members.

Applicants maintain that they have provided a representative number of detailed chemical structures, i.e., the nucleic acid sequence of SEQ ID NO: 5981, and it's complements. The common structural feature (the nucleotide sequence of SEQ ID NO: 5981, its complements and specified variations thereof) is shared by every nucleic acid molecule in the claimed genus, and this feature distinguishes members of the claimed genus from non-members. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as

such. Accordingly, the standard elucidated in *University of Cal. v. Eli Lilly* for the written description requirement has been met.

Moreover, Applicants identify not only SEQ ID NO: 5981 but closely related nucleic acid molecules falling within the scope of the present claims - they either share the recited percent sequence identity to SEQ ID NO: 5981 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. The Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed.

The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.

V. Rejection under 35 U.S.C. § 102(e)

Claims 1, and 8-13 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Cohen *et al.* (US 6,476,208 B1, filing date March 20, 2000) ("Cohen, *et al.*"). In particular, the Examiner alleges that "Cohen teach a nucleic acid sequence molecule comprising a sequence that is a fragment of or a complement of the sequence of SEQ ID NO: 5981 (see SEQ ID NO: 129)." Office Action at page 8. To facilitate prosecution Claim 1 has been amended in the present response to delete the recitation of "fragment thereof." Applicants respectfully traverse this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). In the present application, amended claim 1 is directed to substantially purified nucleic acid molecule that encodes a soybean protein comprising a nucleic acid sequence of SEQ ID NO: 5981. The reference cited by the Examiner does not disclose SEQ ID NO: 5981 in its entirety.

Moreover, claims 8-13 are directed to substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof, or

having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. Again, whatever else Cohen *et al.* teaches, it does not describe a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5981 or a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

As such, the presently amended claims are not anticipated by Cohen, *et al.*, cited by the Examiner, and accordingly, for at least the foregoing reasons, the rejection of claims 1 and 8-13 under 35 U.S.C. § 102(e) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5085 with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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